



MEMORANDUM

TO: All Vaccine Providers

FROM: Phil Griffin, Deputy Director
Bureau of Disease Control and Prevention

DATE: November 30, 2015

RE: Meningococcal Serogroup B Vaccines (MenB)

The Advisory Committee on Immunization Practices (ACIP) recently recommended the use of Meningococcal Serogroup B (MenB) vaccine to include adolescents and young adults. This was a change from earlier recommendations that the vaccine was to be used only in high risk groups. This special bulletin is designed to provide you with information and references to consider in your practice.

As of the December 2015 vaccine ordering cycle (December 1st – December 7th), you will be able to order this as you do all vaccines for the VFC and CHIP programs in Kansas. We request you consider two specific issues when ordering.

1. MenB is available from two different manufacturers (Novartis/GSK and Pfizer). A unique guidance with this vaccine is that the two different products may not be used interchangeably to complete the vaccination series. If the patient is started on the series with one product, they must complete with that same product. This should be considered when placing your order and consideration should be given to have both products available regardless of the one you may choose to use primarily in your practice. The reason for this is that you may have a patient present to you who has already begun the series with another provider using the product which you have not chosen to be your primary product.
2. When determining the amount of vaccine you plan to have in your inventory, we recommend you select an amount that is about one quarter of your standard HPV vaccine inventory initially. This amount will need to include both MenB vaccines types and with your VFC/CHIP ratio. You may need to adjust this amount in the months to come based on your observation and uptake of the vaccine usage in your practice.
3. Documentation of vaccine administered by type is important. In KSWebIZ Men B will be documented as: **MenB-4C Bexsero** and **MenB-FHbp Trumenba**

The following pages provide references and guidance from the CDC and other vaccine expert sources. As always, if you have additional questions, please consult with your regional Kansas Immunization Program Nurse Consultant.

Meningococcal Serogroup B Vaccines (MenB) VFC Resolution No.6/15-1

<http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/2015-06-15-mening.pdf>

Licensed for use: Vaccine to prevent invasive disease caused by *Neisseria meningitidis* serogroup B in individuals 10-25 yrs. Complete licensure information consult the PI on FDA website. No licensure safety or immunogenicity data for concomitant administration of other adolescent vaccines. Based on available data and expert opinion, ACIP recommends Men B may be administered concomitantly with other adolescent vaccines at different anatomical sites.

VFC funded Men B vaccine use for:

Ages 10-18 yrs High Risk for MenB disease		<ul style="list-style-type: none"> Persistent complement component deficiencies (including inherited or chronic deficiencies in C3, C5-C9, properdin, factor H or D or taking eculizumab (Soliris®)) Anatomic or functional asplenia, including sickle cell disease Increased risk of MenB due to outbreak 			
Ages 16-18 yrs. old		<ul style="list-style-type: none"> No high risk condition needs to exist to be vaccination. 			
Vaccine Men B	Manuf.	Age Group	Dosing Schedule	Dose	Site
Bexsero® MenB-4C	Novartis/GSK	10-18 yrs	2 doses at least one month apart; 0 and 1-6 months	.5 ml	IM Deltoid
Supplied	Pre-filled syringes (one or ten per carton)				
Contraindication/Warnings	Hypersensitivity including severe allergic reaction to any component in the vaccine or previous dose of Bexsero Tip cap of the pre-filled syringe contains natural rubber latex which may cause allergic reactions in latex sensitive individuals Pregnancy only given when clearly needed. Pregnancy Registry Novartis Vaccines 1-877-683-4632				
Interchangeability	Not to be used interchangeably with other Men B vaccines to complete a series				
Store @ 35-46 F (2-8C)	Do not expose to light				
Vaccine Men B	Manuf.	Age Group	Dosing Schedule	Dose	Site
Trumenba™ MenB-FHbp	Pfizer	10-18 yrs	3 doses 0,2,6 months	.5 ml	IM Deltoid
Supplied	Pre-filled syringes (five or ten per carton)				
Contraindication/Warnings	Hypersensitivity including severe allergic reaction to any component in the vaccine or previous dose Pregnancy only given when clearly needed. Category B				
Interchangeability	Not to be used interchangeably with other Men B vaccines to complete a series				
Store @ 35-46 F (2-8C)	Stored laid flat to minimize the re-dispersion time. Do not expose to light				

Reference: <http://www.immunize.org/nsit.d/n64/n64.pdf>

Two serogroup B meningococcal (MenB) vaccines were recently licensed by the Food and Drug Administration (FDA) for use in people age 10–25 years. MenB-FHbp (Trumenba; Pfizer Inc.) was licensed in October 2014, and MenB-4C (Bexsero; GSK) in January 2015. On October 23, 2015, *Morbidity and Mortality Weekly Report (MMWR)* published “Use of Serogroup B Meningococcal Vaccines in Adolescents and Young Adults: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2015,” available at www.cdc.gov/mmwr/pdf/wk/mm6441.pdf, pages 1171–6. These recommendations were voted upon and approved at the June 2015 ACIP meeting. The recommendations state that adolescents and young adults age 16–23 may be vaccinated with MenB vaccine to provide short-term protection against most strains of serogroup B meningococcal disease. The preferred age for MenB vaccination is 16–18 years. The new MenB recommendations are classified as Category B, meaning the recommendations allow for individual clinical decision making. (Vaccines with Category A recommendations are made for all persons in an age- or risk-factor based group.) The Category B classification enables coverage by the Vaccines For Children program and most insurance plans. MenB vaccine should be administered either as a 3-dose series of MenB-FHbp (Trumenba) or a 2-dose series of MenB-4C (Bexsero). The two MenB vaccines are not interchangeable; the same vaccine product must be used for all doses. On the basis of available data and expert opinion, MenBFHbp or MenB-4C may be administered concomitantly with other vaccines indicated for this age, but at a different anatomic site, if feasible. In addition to the Category B recommendation for adolescents and young adults, CDC also has issued recommendations for routine use (i.e., Category A) of MenB vaccines in certain groups of people at increased risk for serogroup B meningococcal disease. (Available at <http://www.cdc.gov/mmwr/pdf/wk/mm6422.pdf%20> page 608)

These groups include:

- People age 10 years and older who have functional or anatomic asplenia
- People age 10 years and older who have persistent complement component deficiency
- People age 10 years and older who are at risk during an outbreak caused by a vaccine serogroup, such as on college campuses
- Microbiologists who work with meningococcus bacteria in a laboratory Even though both MenB vaccines are FDA licensed for people 10 through 25 years of age, ACIP recommends the vaccines can be used off label for those at increased risk of serogroup B meningococcal disease who are 26 years of age or older.

In contrast to meningococcal conjugate vaccine (MCV4 [MenACWY]) recommendations, MenB vaccine is not routinely recommended for college students or international travelers.

Q&As regarding the use of both MCV4 and MenB in adolescents are available on the CDC website at:

<http://www.cdc.gov/vaccines/vpd-vac/mening/faqs-hcp-adolescent-vaccine.html>

Before administering serogroup B meningococcal vaccine, providers should consult the package insert ([Bexsero®](#) or [Trumenba®](#)) for precautions, warnings, and contraindications. For a summary of contraindications and precautions, see the [Serogroup B Meningococcal Vaccine Information Statement](#).